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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER

5

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/585,475	Andersen et al.
Examiner	**Art Unit**
Peter Tung	1652

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-84* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-84* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐	Notice of References Cited (PTO-892)	18 ☐	Interview Summary (PTO-413) Paper No.s.
16) ☐	Notice of Draftsperson's Patent Drawing Review (PTO-948)	19 ☐	Notice of Informal Patent Application (PTO-152)
17) ☐	Information Disclosure Statement s (PTO-1449) Paper No.s	20 ☐	Other

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, drawn to a method for determining a degree of toxicity of an agent, classified in class 435, subclass 4.

II. Claim 14 drawn to a protein toxicity marker selected from the proteins of Table 8, classified in class 530, subclass 350.

III. Claims 15, 20 and 21, drawn to protein toxicity marker, classified in class 530, subclass 350.

IV. Claim 16, drawn to a binding reagent specific for a protein selected from protein toxicity markers of Table 8, classified in class 530, subclass 300.

V. Claim 17,22 and 23, drawn to a binding reagent specific for a protein selected from protein toxicity markers, classified in class 530, subclass 300.

VI. Claims 18 and 19, drawn to a method of monitoring efficacy in a subject exposed to an agent, classified in class 435, subclass 4.

VII. Claims 24 and 25, drawn to a method for screening compounds for blood cholesterol regulating activity, classified in class 435, subclass 4.

VIII. Claim 26, 29 and 32, drawn to a pharmaceutical composition for reducing blood cholesterol levels, classified in class 514, subclass 2.

IX. Claims 27 and 28, drawn to a method for reducing blood cholesterol levels, classified in class 514, subclass 2.

X. Claims 30 and 31, drawn to a method for screening compounds for blood cholesterol regulating activity, classified in class 435, subclass 4.

XI. Claims 33-35, drawn to a a method of identifying biological pathways in a cell affected by an agent, classified in class 435, subclass 4.

XII. Claims 36 and 37, drawn to a standardized two-dimensional electrophoretic distribution of proteins, classified in class 530, subclass 412.

XIII. Claims 38, 39 and 41 drawn to a method for identifying a toxic response marker, classified in class 435, subclass 4.

XIV. Claim 40, 60 and 75 drawn to a protein toxicity marker, classified in class 530, subclass 350.

XV. Claims 42, 43, 61 and 76, drawn to a binding reagent specific for a protein toxicity marker, classified in class 530, subclass 300.

XVI. Claims 44-47, drawn to a method for evaluating the toxicity of an antilipemic agent, classified in class 435, subclass 4.

XVII. Claims 48-50, drawn to a method for determining drug toxicity susceptibility markers, classified in class 435, subclass 4.

XVIII. Claim 51 and 52, drawn to a protein susceptibility marker, classified in class 530, subclass 350.

XIX. Claims 53 and 54, drawn to a binding reagent specific for a protein susceptibility marker, classified in class 530, subclass 300.

XX. Claims 55-59, drawn to a method for determining a protein marker when the protein is not a statistically significant marker, classified in class 435, subclass 4.

XXI. Claims 62-66, drawn to a method for determining whether a combination of proteins form a protein marker, classified in class 435, subclass 4.

XXII. Claim 67, drawn to a a combination of proteins, classified in class 530, subclass 350.

XXIII. Claim 68, drawn to a method for finding drug development targets, classified in class 435, subclass 5.

XXIV. Claim 69, 72 and 73, drawn to a drug development target, classified in class 530, subclass 350.

XXV. Claims 70 and 71, drawn to a binding reagent specific for a drug development target, classified in class 530, subclass 300.

XXVI. Claim 74, drawn to a method for determining whether a protein is a protein marker, classified in class 435, subclass 4.

XXVII. Claim 77 and 78, drawn to a method for generating an index marker, classified in class 435, subclass 4.

XXVIII. Claim 79, drawn to an antisense compound, classified in class 536, subclass 24.5.

XXIX. Claim 80, drawn to a method for confirming protein markers, classified in class 435, subclass 4.

XXX. Claim 81, drawn to a method for determining the synergistic or additive action of pharmaceuticals, classified in class 514, subclass 1.

XXXI. Claim 82, drawn to a synergistic pharmaceutical composition, classified in class 514, subclass 1.

XXXII. Claims 83 and 84, drawn to a method for determining a reaction to an agent, classified in class 435, subclass 4.

2. The inventions are distinct, each from the other because of the following reasons Each of Groups II-VI, VII, XII, XIV, XV, XVII, XIX, XXII, XXIV, XXV, XXVIII and XXXI, is directed to a separate and distinct invention. Each of the Groups is directed to a separate and distinct product, as listed supra.

The products of Groups II-VI, VII, XII, XIV, XV, XVII, XIX, XXII, XXIV, XXV, XXVIII and XXXI would be expected to have distinct morphological, functional, chemical and physical properties as indicated by their divergent classification, process of making and process of using. These products are capable of separate manufacture, use, or sale as claimed, and are patentably distinct.

3. Each of Groups I, VII, IX, X, XI, XIII, XVI, XVII, XX, XXI, XXIII, XXVI, XXVII, XXIX, XXX and XXXII is directed to a separate and distinct invention. Each of the Groups is directed to a separate and distinct method, as listed supra. These methods are distinct both

physically and functionally, require different process steps, reagents and parameters and produce different products.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.